



caBIG™ cancer Biomedical
Informatics Grid™

Reporting/Sharing Special Interest Group Meeting

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NCI Center for Biomedical Informatics and Information Technology

caBIG™ Clinical Trials Management Systems Workspace

August 29, 2007

U.S. DEPARTMENT
OF HEALTH AND
HUMAN SERVICES

National Institutes
of Health

May 2007



- **Meeting Objectives**
- **Introductions**
- **SIG Meeting Schedule**
- **Overview of CTMS Workspace**
- **Overview of Reporting / Sharing SIG**
- **Clinical Trials Database (CTDB)**
- **Comment, Feedback, Questions**
- **Review of Action Items**

- **Overview of the Clinical Trial Management Systems (CTMS) Workspace**
- **Overview of the Reporting/Sharing SIG Activities and Projects**
- **Introduction of the current Reporting/Sharing Task Force**
- **Overview of the Clinical Trials Database (CTDB)**
 - **Proposed First Iteration**
 - **Next Steps**

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- **SIG Lead:** **Christo Andonyadis**
NCI Center for Biomedical Informatics and Information
Technology (NCI CBIIT)
andonyac@mail.nih.gov
- **SIG Facilitator:** **Karen Ryan**
Booz Allen Hamilton (BAH)
ryan_karen@bah.com
- **SIG Support:** **Ryan Budd**
Booz Allen Hamilton (BAH)
budd_ryan@bah.com

Meeting Schedule for SIG



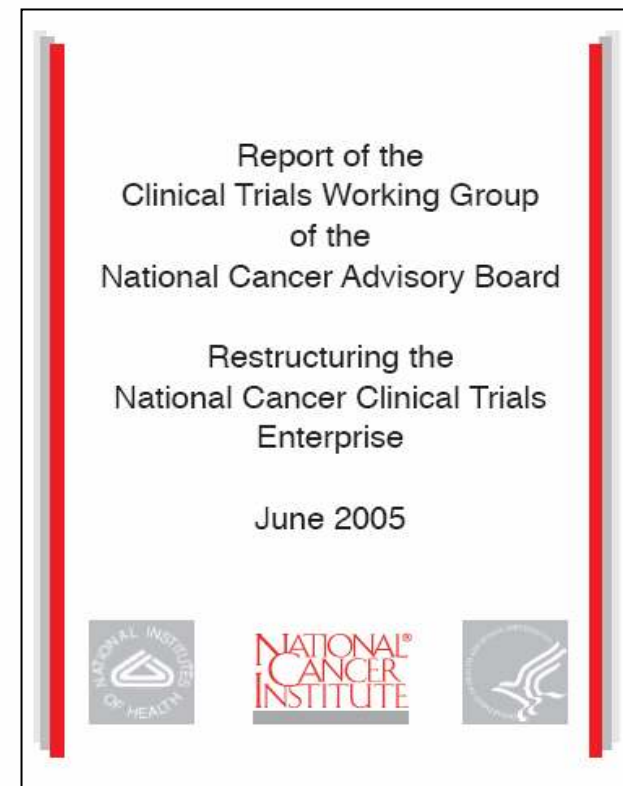
- All SIG calls are open to the community
- Listserv: CABIG_CTMS_REPT_SIG@LIST.NIH.GOV

<i>Meeting</i>	<i>Call Schedule</i>
Reporting/Sharing SIG	4th Wednesday each month; 3:00-5:00pm ET

- All SIG meetings are open to the community
- Information on the SIG meetings are posted to the Listserv (https://list.nih.gov/archives/cabig_ctms_rept_sig.html)
- SIG Members are encouraged to provide input and feedback on the projects via the following mechanisms:
 - Participate in SIG calls, Workspace calls and face-to-face meetings
 - Participate in community demonstrations of applications that are under development (announced via the CTMS and SIG Listserv)
 - Contact a Reporting / Sharing Task Force member
 - Contact a Steering Committee member
 - Contact SIG Lead or Facilitator
 - Contact CTMS Workspace Lead

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- National Cancer Advisory Board Group
- Report “Re-engineering the Cancer Clinical Research Enterprise” (*June 2005*)
- Remit: advise on “*whether, and in what ways, the NCI-supported national clinical trials enterprise should be restructured to realize the promise of molecular medicine for advancing oncologic clinical practice in the 21st Century*”



Clinical Trials Working Group (CTWG)



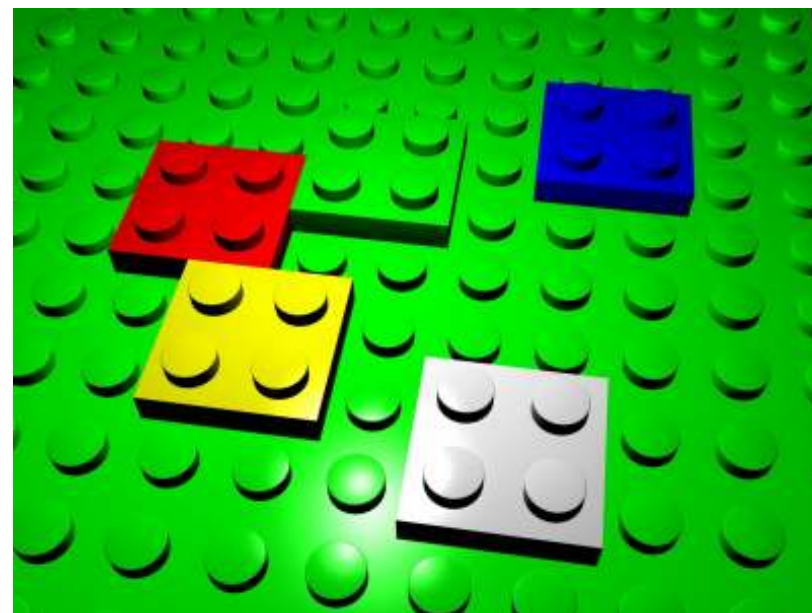
CTWG Goals	CTWG Informatics Initiatives
Enhanced Coordination	Establish a comprehensive database containing regularly-updated information on all NCI-funded clinical trials
Enterprise-wide Standardization	Achieve industry and FDA concurrence on standard Case Report Forms incorporating Common Data Elements
	Promote establishment of national clinical trial information technology infrastructures that are fully interoperable with NCI's cancer Biomedical Informatics Grid (caBIG™)
	Develop a credentialing system for investigators and sites that is recognized and accepted by NCI, industry sponsors, clinical investigators, and clinical trial sites

- Facilitate the **planning** and instantiation of clinical trials, (and **monitoring** of trials once they are instantiated)
- Facilitate the **conduct** of clinical trials
- Facilitate the **reporting and sharing** of clinical trial data to existing/ new destinations
- Achieve **interoperability**
 - Increase the ability of systems to *access* and *use* the data and functionality of other systems
 - Facilitate the integration of new sources and destinations of data

caBIG™'s Special Sauce: Modularity Implies Interoperability



- Building for the next ten years: Need to interface rapidly with new data sources and destinations
- Only a set of interoperable modules is agile enough to handle the speed of science
- Anyone can build a module that plugs in – if they build to published caBIG™ standards
- Modularity implies interoperability



CTMS Workspace Organization



Planning/ Monitoring

- Investigator and Site Credential Repository
- Study Initiation Tool
- Protocol Lifecycle Tracking
- FIREBIRD
- DCP/DESK

Study Conduct

- Standardized Case Report Forms
- Cancer Central Clinical Database (C3D)
- Participant Registry
- Laboratory Interface
- Financial/Billing
- Study Calendar
- Subject Prescreening
- Vendor Systems

Reporting/ Sharing

- Clinical Trials Database
- Routine Data Exchange
- Clinical Trials Object Model (CTOM)
- Janus (FDA Repository)
- Adverse Event Reporting and Collection (caAERS)
- AE Expedited Reporting (AdEERS)
- Clinical Data System (CDS)

Interoperability

- System Interoperability and Harmonization
- Biomedical Research Integrated Domain Group (BRIDG) model
- caBIG™ Clinical Trials Suite (Clinical Trials Interoperability Project)

CTMS SIGs: Telcon Schedule and Listservs



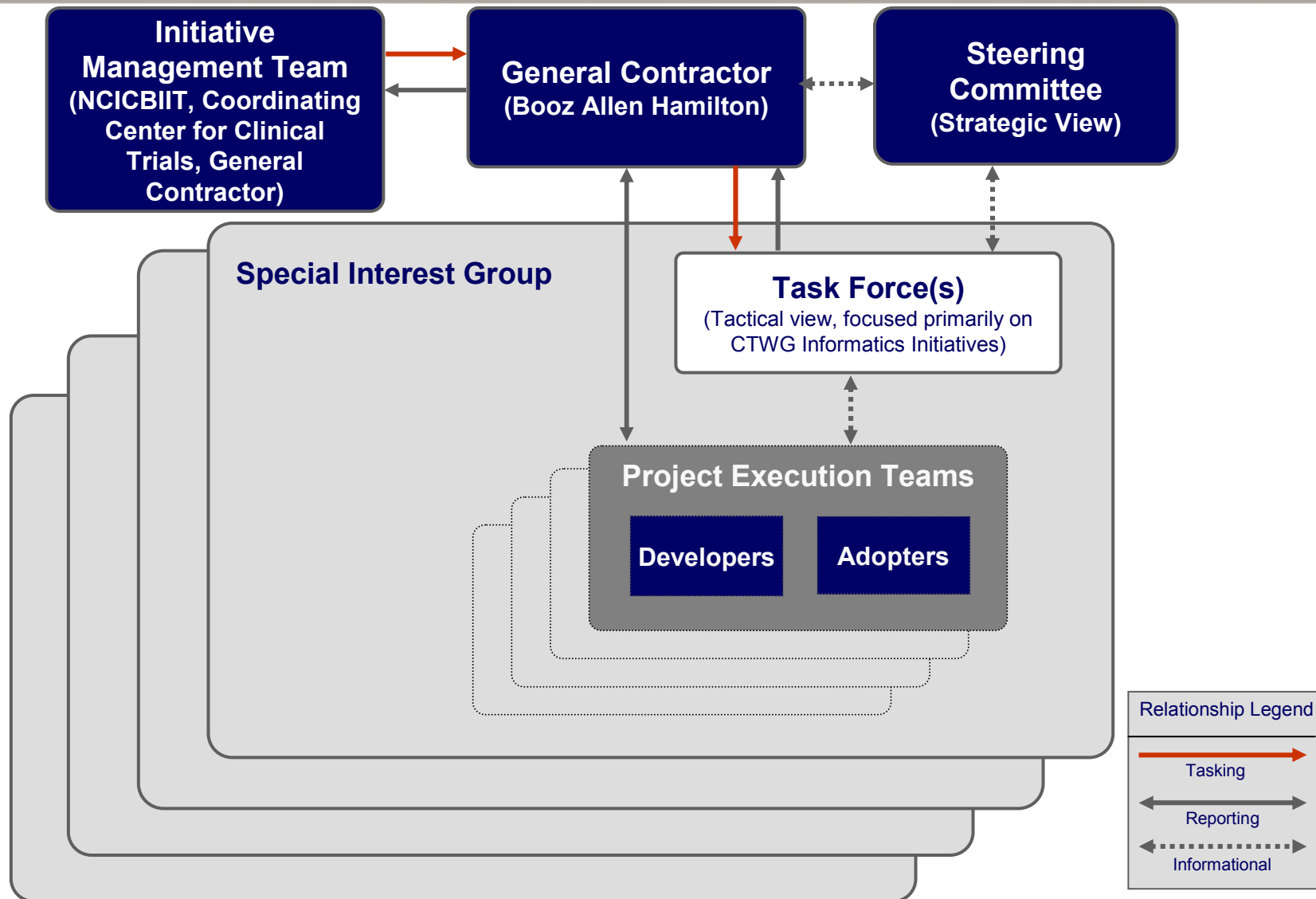
SIG	Teleconference	Listserv (http://list.nih.gov)
Planning / Monitoring	3 rd Tuesdays 2:00 – 4:00 PM EDT	CABIG_CTMS_PLAN_SIG@LIST.NIH.GOV
Study Conduct	3 rd Wednesdays 3:00 – 5:00 PM EDT	CABIG_CTMS_COND_SIG@LIST.NIH.GOV
Reporting / Sharing	4 th Wednesdays 3:00 – 5:00 PM EDT	CABIG_CTMS_REPT_SIG@LIST.NIH.GOV
Interoperability	4 th Tuesdays 2:00 – 4:00 PM EDT	CABIG_CTMS_INTR_SIG@LIST.NIH.GOV

CTMS SIG Listservs: How To Subscribe



- Browse lists at NIH Listserv List page (https://list.nih.gov/cgi-bin/show_list_archives).
- Select Listserv of choice
- Click on “Join or leave the list, or update options”
- Enter Email address and full name and click on “Join the List.”
- Upon receipt of confirmation Email, click on link provided within the Email to finalize subscription.
- To unsubscribe from any list, please visit the NIH Listserv List page and click on the specific listserv link. Click on “Leave the List”, enter email address and full name, and click on “Leave the List.”

CTMS Workspace Management



CTMS Web Page

<https://cabig.nci.nih.gov/workspaces/CTMS>



Clinical Trials Management Systems (CTMS) Workspace — Microsoft Internet Explorer

File Edit View Favorites Tools Help

Address <https://cabig.nci.nih.gov/workspaces/CTMS/?pid=primary.2006-10-24.9768040952&sid=ctmsws&status=True> Go Links >>

Search Web Search Mail My Yahoo! Shopping Games Music Answers >>

National Cancer Institute U.S. National Institutes of Health | www.cancer.gov

caBIG™ Cancer Biomedical Informatics Grid™

Home
About caBIG™
Events & Calendar
Community News
Policies, Guidelines & Whitepapers
Compatibility & Certification
Tools, Infrastructure, Data Resources
Library
Training Portal
Workspaces & SIGs
Domain Workspaces
Clinical Trial Management Systems
Interoperability SIG
Planning/Monitoring SIG
Reporting/Sharing SIG
Study Conduct SIG
Integrative Cancer Research
In Vivo Imaging
Tissue Banks and Pathology Tools

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Clinical Trials Management Systems (CTMS) Workspace

The Clinical Trials Management Systems (CTMS) Workspace is developing a comprehensive set of modular, interoperable and standards-based tools designed to meet diverse clinical trials management needs and respond to four informatics-focused recommendations made by NCI's [Clinical Trials Working Group](#) (CTWG). For more information on the CTWG's four informatics-focused recommendations, click [here](#).

New to the Clinical Trials Management Systems (CTMS) Workspace? Check out the [CTMS Newcomer Information](#) section.

Looking for a review of recent caBIG™ activities?

[caBIG™ Links](#): The monthly newsletter provides brief articles on ways in which institutions are implementing caBIG™ products, as well as recent developments in the caBIG™ initiative.

Archived [Program Updates](#) (December 2003 – January 2007) include information on progress within the caBIG™ initiative and highlights from the workspaces.

CTMS Materials

- [Schedule](#) (for teleconferences)
- [Meeting Notes](#) (from teleconferences)
- [Face-to-Face Meeting Materials](#) (2004 to present)
- [Contact Information](#)

CTMS Participant Shortcuts

- [Meeting Notes](#)
- [Schedule](#)
- [Contact Information](#)
- [Templates & Forms](#)
- [CTMS Listserv](#)
- [CTMS home on GForge](#)

CTMS Product Shortcuts

Tools

- [Cancer Central Clinical Database \(C3D\)](#)
- [Cancer Central Clinical Participant Registry \(C3PR\)](#)
- [Clinical Data System](#)
- [Lab Integration Hub \(caXchange\)](#)

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Reporting / Sharing Task Force Members (Current)








James Anderson, Ph.D.	University of Nebraska
Rhoda Arzoomanian, R.N.	University of Wisconsin
Dawn Caron-Fabio	Memorial Sloan-Kettering Cancer Center
John Ellerton, M.D.	Nevada Community Clinical Oncology Program
Shanda Finnigan, R.N.	NCI Cancer Therapy Evaluation Program (CTEP)
Steve Friedman	NCI Cancer Therapy Evaluation Program (CTEP)
Lakshmi Grama	NCI Office of Communication and Education
Tad McKeon	St. Jude Children's Research Hospital
Randy Millikan, M.D., Ph.D.	MD Anderson
Bob Morrell	Wake Forest University
Diane Paul	Consumer Advocates in Research and Related Activities (CARRA)
George Redmond	NCI Cancer Therapy Evaluation Program (CTEP)
Ann Setser, R.N.	NCI Cancer Therapy Evaluation Program (CTEP)
Anne Tompkins, R.N.	NCI Division of Cancer Prevention (DCP)
Brenda Young, R.N.	American College of Radiology
Jamie Zwiebel, M.D.	NCI Cancer Therapy Evaluation Program (CTEP)

Clinical Trials Working Group Informatics Initiative

- A comprehensive, community accessible database that will contain complete, up-to-date information (e.g., status, protocol, accrual, adverse events, toxicity, efficacy) on all NCI-supported clinical trials
 - Prioritization enhanced, duplication of effort reduced by full picture of cancer clinical trials enterprise
 - Patient accrual enhanced through better physician/patient access to clinical trials data
 - Rapid dissemination of toxicity / adverse event information
 - Rapid dissemination of patterns of favorable outcomes
- Designed and implemented in accordance with caBIG[™] principles / standards
- NCI Center for Biomedical Informatics and Information Technology will design data submission procedures in consultation with NCI program staff and representatives of the extramural community
- Long-term goal: include information on trials funded by other public- and private-sector sponsors

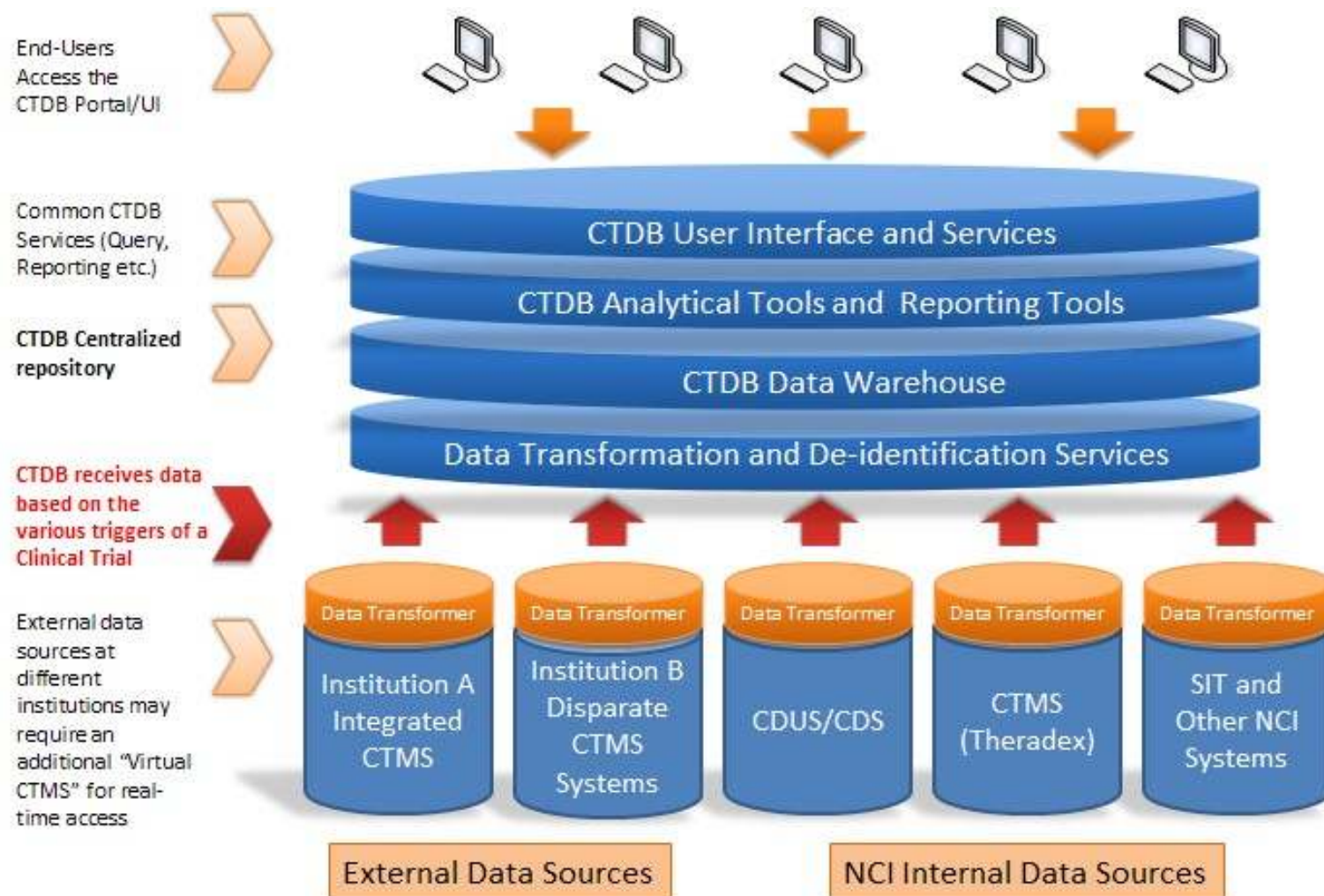
- **Initiated June 2006**
- **Reviewed scope**
- **Architectural options**
 - Central
 - Distributed
 - Hybrid
- **Suspended October 2006**
- **caBIG CTMS Restructuring**
- **Proposed first (central) iteration**
 - Register all trials
 - Including protocol document
 - Classification to support Summary 4 reporting
 - Accrual data
 - CDUS Abbreviated style
 - Built on top of CTOM for easy extension

The SIG completed the following key Inception activities:

-  Vision
-  Scope
-  Use Cases (in progress)
-  Requirements (in progress)
-  Candidate Architecture (in progress)

Development and refinement of Use Cases, Requirements and Candidate Architecture are conducted in an iterative fashion. The CTDB SIG in conjunction with the CTDB Project Team has completed an initial pass through the Use Cases, Requirements and Candidate Architecture.

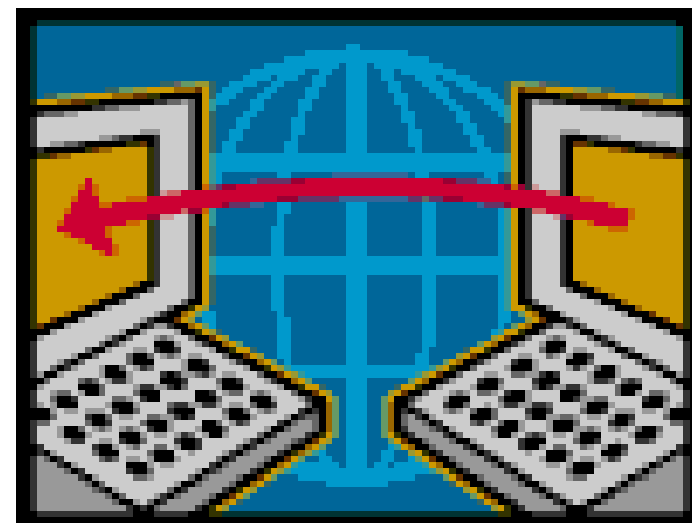
Centralized Candidate CTDB Architecture



Routine Data Exchange – Pilot SIG



- Defining the requirements for a regulatory reporting interface module that will facilitate the submission of clinical trial reports electronically to NCI's CDUS (Clinical Data Update System) and the NCI's Clinical Trial Monitoring Service (CTMS).
- Capture relevant data from multiple systems and in multiple formats and translate them into the required formats. The process will be automated as much as possible to improve workflow and minimize manual operations.
- Allows retention of data that is lost under current reporting mechanisms to improve and facilitate internal analysis of ongoing studies.



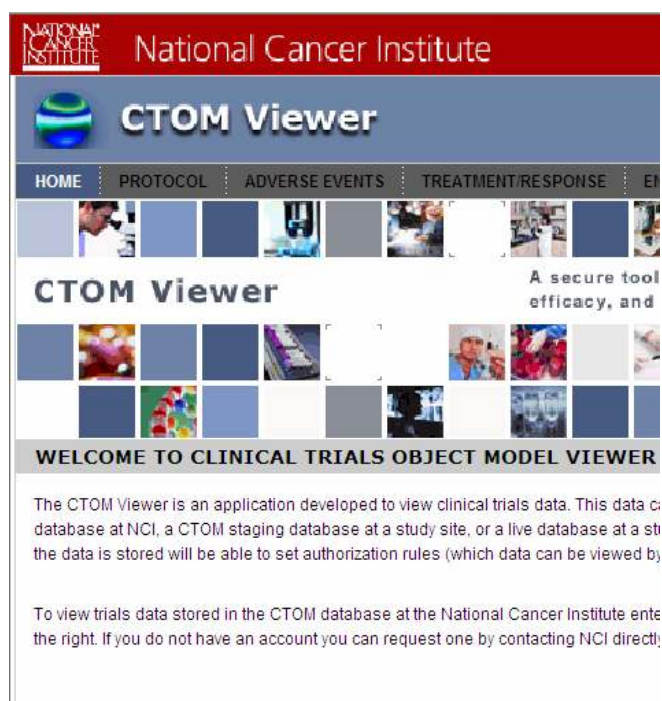
- **Reporting Recommendations Whitepaper**
 - Clinical Trials Monitoring Service (CTMS) and Clinical Data Update System (CDUS) data elements (CDEs) should be harmonized
 - Support for cumulative as well as incremental updates
 - CTMS currently supports only incremental
 - CDUS currently supports only cumulative
 - Submitted data available made available in standard reports
 - Data should be sent securely
- **Summary 3 & 4 Issues**
 - Proposed definition of “Therapeutic Trial”
 - ***Those trials in which a study agent, device or other intervention is used with the intention of curing or preventing disease or prolonging or otherwise improving the life of the subject on the trial.***
 - Disease Site list should include all ICD-O

Summary 4 Columns



- **Group/Sponsor/Funding Source**
- **Anatomic Site (Site)**
- **Protocol ID/IRB Number**
- **Principal Investigator (PI)**
- **Program (Prog) – as defined in Summary 1B**
- **Date Opened - opened to accrual or initiated**
- **Date Closed -closed to accrual or completed**
- **Phase - pilot, feasibility, 1, 2, 3,4, or combinations such as ½ and N/A**
- **Trial/Study Type (Type)**
 - **Therapeutic intervention (Ther)**
 - **Prevention intervention (Prev)**
 - **Screening, Early Detection, or Diagnostic (Screen, Detect, Diag)**
 - **Supportive Care (Supp)**
 - **Epidemiologic/Observational (Epi,Obs)**
 - **Ancillary or Companion (Anc, Comp)**
 - **Correlative (Corr)**
- **Title**
- **Target Accrual**
- **Accrual Site – Center and Other**
- **Accrual Timeframes – 12 months and To Date**

Clinical Trials Object Model (CTOM)



- **CTOM is a common model of clinical trials data**
 - Focused on outcomes
 - Assessments, observations and findings
 - BRIDG harmonized
- **Standardize on the model, not the database**
- **CTOM uses caBIG technology (caAdapter, caCORE SDK generated Java Application Program Interfaces) to support:**
 - Mapping of local data sources to CTOM
 - Sharing of local data via CTOM APIs
- **CTOM APIs have already been mapped to:**
 - CTOM database
 - Janus database
- **CTOM Viewer uses CTOM APIs to access data**
- **CTOM database populated with CTMS/Theradex data files**

FDA's JANUS Submission Data Repository Model

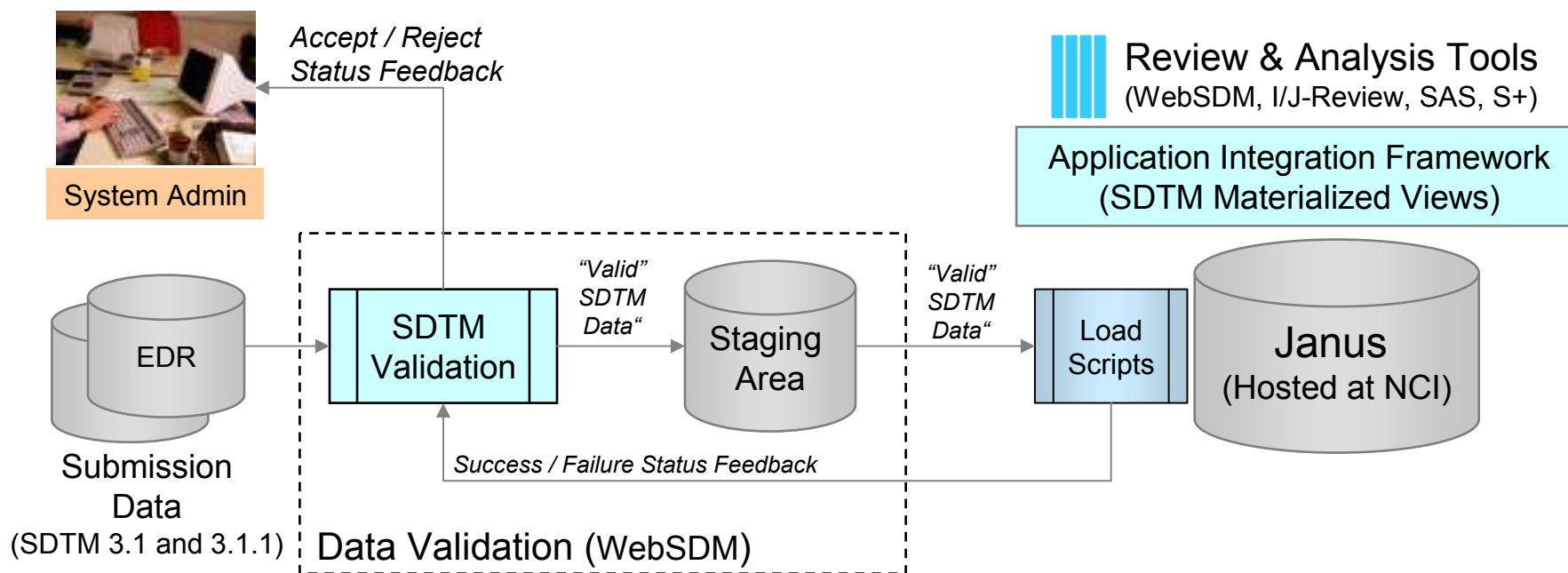


- Original concept and design by Norman Stockbridge and Jonathan (Jay) Levine of FDA/CDER, 1999.
- Lincoln Technologies developed an early prototype implementation in 2001.
- Key concepts integrated into CDISC data standardization efforts, leading to release of SDTM 1.0 and Implementation Guide 3.1 in July 2004.
- FDA and IBM designed the current Janus clinical data submission repository
 - Worked under a Cooperative R&D Agreement (CRADA), completed in 2004
 - Janus logical data model published: <http://www.fda.gov/oc/datacouncil/>
- IBM implemented a Janus prototype for FDA and NCI
 - FDA and NCI cooperating through an Interagency Oncology Task Force (IOTF)
 - Testing completed in January 2006
- IBM is currently implementing a Janus Operational Prototype for FDA and NCI

- **An infrastructure that will:**
 - allow secure transmission of clinical research information between sponsors, researchers, and regulatory authorities;
 - facilitate the adoption of electronic data standards, standardized terminologies, e-transactions, and e-submissions;
 - reduce the overall cost of existing information gathering and submissions development processes as well as review and analysis of information; and
 - be accessible to all.

High Level Architecture

Operational Prototype for FDA



Cancer Adverse Event Reporting System (caAERS)



- **Module 1: Adverse Event Data Capture**
 - Information entered through a web interface, the system captures the severity of the adverse event and provides instructions for further reporting
 - Internal reporting capabilities allow the CRA to follow submissions, Quality Assurance to review them, and the Principal Investigator(s) to monitor toxicities and address further reporting requirements
- **Module 2: Interface between AE Capture Tool & Local Clinical Trials Databases**
 - Facilitates communication between module 1 database and the participating institution's clinical trials database

caAERS cancer Adverse Event Reporting System

Adverse Events Studies Participants Reports Rules Administration

Tasks: Enter expedited report List reports Enter routine report

1. Begin 2. Categories 3. Adverse Events 4. Save

Create Routine AE: Select Ctc Categories

Summary

Participant Ronald McDonald (899889889)

Study Test Study August 8 (NCT777333)

Primary AE None

Adverse event 0 count

Categories

Please select the CTC Categories for Ronald McDonald on

Periods of Observation

*From: *To:

ALLERGY/IMMUNOLOGY GASTROINTESTIN
AUDITORY/EAR GROWTH AND DE
BLOOD/BONE MARROW HEMORRHAGE/BL
CARDIAC ARRHYTHMIA HEPATOBIILIARY/I
CARDIAC GENERAL INFECTION
COAGULATION LYMPHATICS
CONSTITUTIONAL SYMPTOMS METABOLIC/LABC
DEATH MUSCULOSKELET
DERMATOLOGY/SKIN NEUROLOGY
ENDOCRINE OCULAR/VISUAL

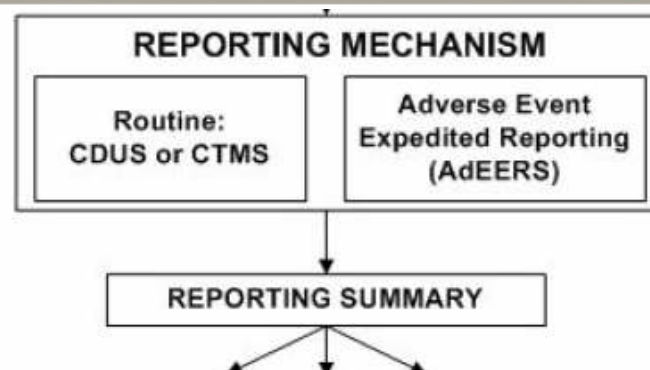
Cancer Adverse Event Reporting System (caAERS)



- **Module 3: Vocabulary Mapping Service**
 - Utilizes mappings from the CTMS Metadata/Vocabulary project to support customized reports and forms
 - Common Toxicity Criteria (CTC)/MedDRA mappings supported in searches on AE category and term during data capture and for reporting
- **Module 4: External Agency Reporting**
 - Expanded functionality for electronically communicating SAEs to participating entities/systems such as AdEERS
 - Provides generic alert messages to national cooperative groups and industrial sponsors involved with NCI funded protocols

The screenshot displays the caAERS (cancer Adverse Event Reporting System) web interface. At the top, the header includes the caAERS logo and navigation tabs for Adverse Events, Studies, Participants, Reports, and Rules. Below the header, a 'Tasks' bar offers options: 'Enter expedited report', 'List reports', and 'Enter routine report'. A progress bar indicates the current step is '3. Adverse Events' within a sequence of '1. Begin', '2. Categories', '3. Adverse Events', and '4. Save'. The main content area is titled 'Create Routine AE: Enter basic AE information'. It is divided into two panels. The 'Summary' panel on the left contains the following information: Participant: Ronald McDonald (899889889), Study: Test Study August 8 (NCT777333), Primary AE: Gastric infection, and Adverse event count: 2. The 'Adverse Events' panel on the right shows a message 'You are entering routine Adverse Event' and a list of categories: BLOOD/BONE MARROW, GASTROINTESTINAL, INFECTION, and PAIN. The 'PAIN' category is selected, and a sub-list of pain types is visible: Pain - Chest wall, Pain - Chest/thorax NOS, Pain - Dental/teeth/periodontal, Pain - Esophagus, and Pain - External ear.

CTEP Adverse Event Reporting



ATTRIBUTION	GRADE 1		GRADE 2		GRADE 3		GRADE 4		GRADE 5	
	UNEXPECTED	EXPECTED	UNEXPECTED	EXPECTED	UNEXPECTED	EXPECTED	UNEXPECTED	EXPECTED	UNEXPECTED	EXPECTED
UNRELATED	CTMS	CTMS	CTMS	CTMS	CTMS CDUS	CTMS CDUS	CTMS CDUS AdEERS	CTMS CDUS AdEERS	CTMS CDUS AdEERS	CTMS CDUS AdEERS
UNLIKELY	CTMS	CTMS	CTMS	CTMS	CTMS CDUS	CTMS CDUS	CTMS CDUS AdEERS	CTMS CDUS AdEERS	CTMS CDUS AdEERS	CTMS CDUS AdEERS
POSSIBLE	CTMS CDUS	CTMS CDUS	CTMS CDUS AdEERS	CTMS CDUS	CTMS CDUS AdEERS	CTMS CDUS	CTMS CDUS AdEERS	CTMS CDUS AdEERS	CTMS CDUS AdEERS	CTMS CDUS AdEERS
PROBABLE	CTMS CDUS	CTMS CDUS	CTMS CDUS AdEERS	CTMS CDUS	CTMS CDUS AdEERS	CTMS CDUS	CTMS CDUS AdEERS	CTMS CDUS AdEERS	CTMS CDUS AdEERS	CTMS CDUS AdEERS
DEFINITE	CTMS CDUS	CTMS CDUS	CTMS CDUS AdEERS	CTMS CDUS	CTMS CDUS AdEERS	CTMS CDUS	CTMS CDUS AdEERS	CTMS CDUS AdEERS	CTMS CDUS AdEERS	CTMS CDUS AdEERS

CDUS – CLINICAL DATA UPDATE SYSTEM for Routine Reporting

CTMS – CLINICAL TRIALS MONITORING SERVICE for Routine Reporting

AdEERS – EXPEDITED REPORTING (This includes hospitalization [or prolongation of existing hospitalization] for any event equivalent to CTC Grade 3, 4, 5 which precipitated hospitalization regardless of requirements for Phase of study, expected or unexpected, and attribution.)

Phase 1 Trials AdEERS Reporting Timelines



3.4.1 Phase 1 Trials utilizing an Agent under a CTEP IND: AdEERS Expedited Reporting Requirements for Adverse Events that occur within 30 Days of the Last Dose of the Investigational Agent

Table C: Reporting Requirements for Adverse Events that occur within 30 Days¹ of the Last Dose of the Investigational Agent on Phase 1 Trials

	1	2	2	3		3		4 & 5 ²
	Unexpected and Expected	Unexpected	Expected	Unexpected with Hospitalization	Unexpected without Hospitalization	Expected with Hospitalization	Expected without Hospitalization	Unexpected and Expected
Unrelated Unlikely	Not Required	Not Required	Not Required	10 Calendar Days	Not Required	10 Calendar Days	Not Required	24-Hour; 5 Calendar Days
Possible Probable Definite	Not Required	10 Calendar Days	Not Required	24-Hour; 5 Calendar Days	24-Hour; 5 Calendar Days	10 Calendar Days	Not Required	24-Hour; 5 Calendar Days

¹Adverse events with attribution of possible, probable, or definite that occur greater than 30 days after the last dose of treatment with an agent under a CTEP IND require reporting as follows:

AdEERS 24-hour notification followed by complete report within 5 calendar days for:

- Grade 3 unexpected events with hospitalization or prolongation of hospitalization
- Grade 4 unexpected events
- Grade 5 expected and unexpected events

²Although an AdEERS 24-hour notification is not required for death clearly related to progressive disease, a full report is required as outlined in the table.

December 15, 2004

Phase 2 & 3 Trials AdEERS Reporting



3.4.2 Phase 2 and Phase 3 Trials utilizing an Agent under a CTEP IND: AdEERS Expedited Reporting Requirements for Adverse Events that occur within 30 Days of the Last Dose of the Investigational Agent

Table D: Reporting Requirements for Adverse Events that occur within 30 Days¹ of the Last Dose of the Investigational Agent on Phase 2 and 3 Trials

	1	2	2	3		3		4 & 5	4 & 5 ²
	Unexpected and Expected	Unexpected	Expected	Unexpected with Hospitalization without Hospitalization		Expected with Hospitalization without Hospitalization		Unexpected	Expected
Unrelated Unlikely	Not Required	Not Required	Not Required	10 Calendar Days	Not Required	10 Calendar Days	Not Required	10 Calendar Days	10 Calendar Days
Possible Probable Definite	Not Required	10 Calendar Days	Not Required	10 Calendar Days	10 Calendar Days	10 Calendar Days	Not Required	24-Hour; 5 Calendar Days	10 Calendar Days

¹ Adverse events with attribution of possible, probable, or definite that occur greater than 30 days after the last dose of treatment with an agent under a CTEP IND require reporting as follows:

AdEERS 24-hour notification followed by complete report within 5 calendar days for:

- Grade 4 and Grade 5 unexpected events

AdEERS 10 calendar day report:

- Grade 3 unexpected events with hospitalization or prolongation of hospitalization
- Grade 5 expected events

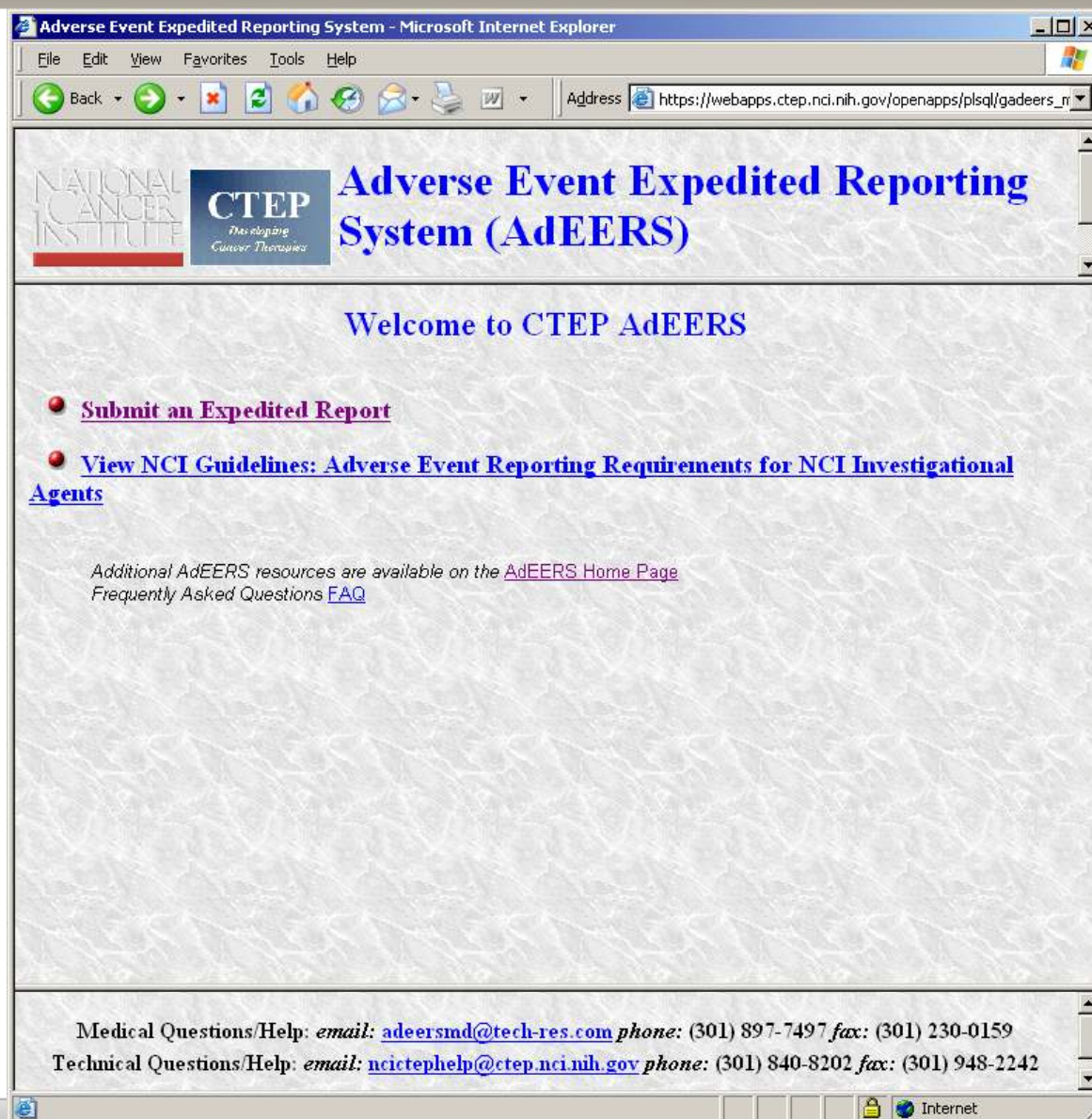
² Although an AdEERS 24-hour notification is not required for death clearly related to progressive disease, a full report is required as outlined in the table.

December 15, 2004

CTEP Adverse Events Reporting



- **Methods of Submission**
 - AdEERS Website
 - AdEERS Web Service (coming soon!)



Clinical Data Update System (CDUS)



- **Quarterly cumulative submission**
- **Methods**
 - **CTEP FTP Site**
 - **Clinical Data System (CDS) Web interface**
- **Abbreviated**
 - **Protocol administrative data**
 - **Patient accrual information**
 - **Patient demographic information**
- **Complete = Abbreviated +**
 - **Prior therapy, baseline abnormalities**
 - **Treatment status & information** (e.g., agent administered, total dose per course)
 - **Adverse event information** (e.g., AE type, grade)
 - **Response information** (e.g., response observed, date response observed)



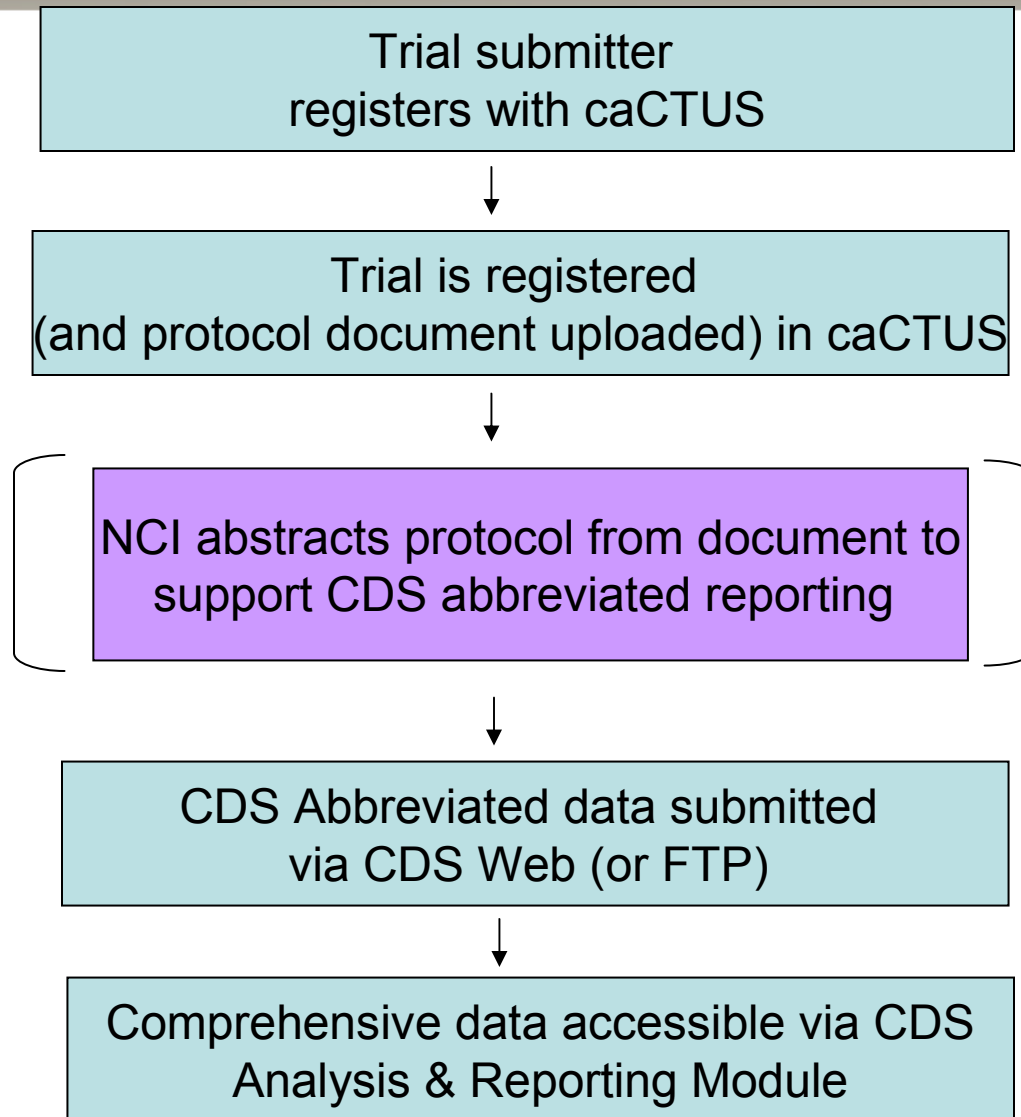
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Proposed First Iteration of CTDB

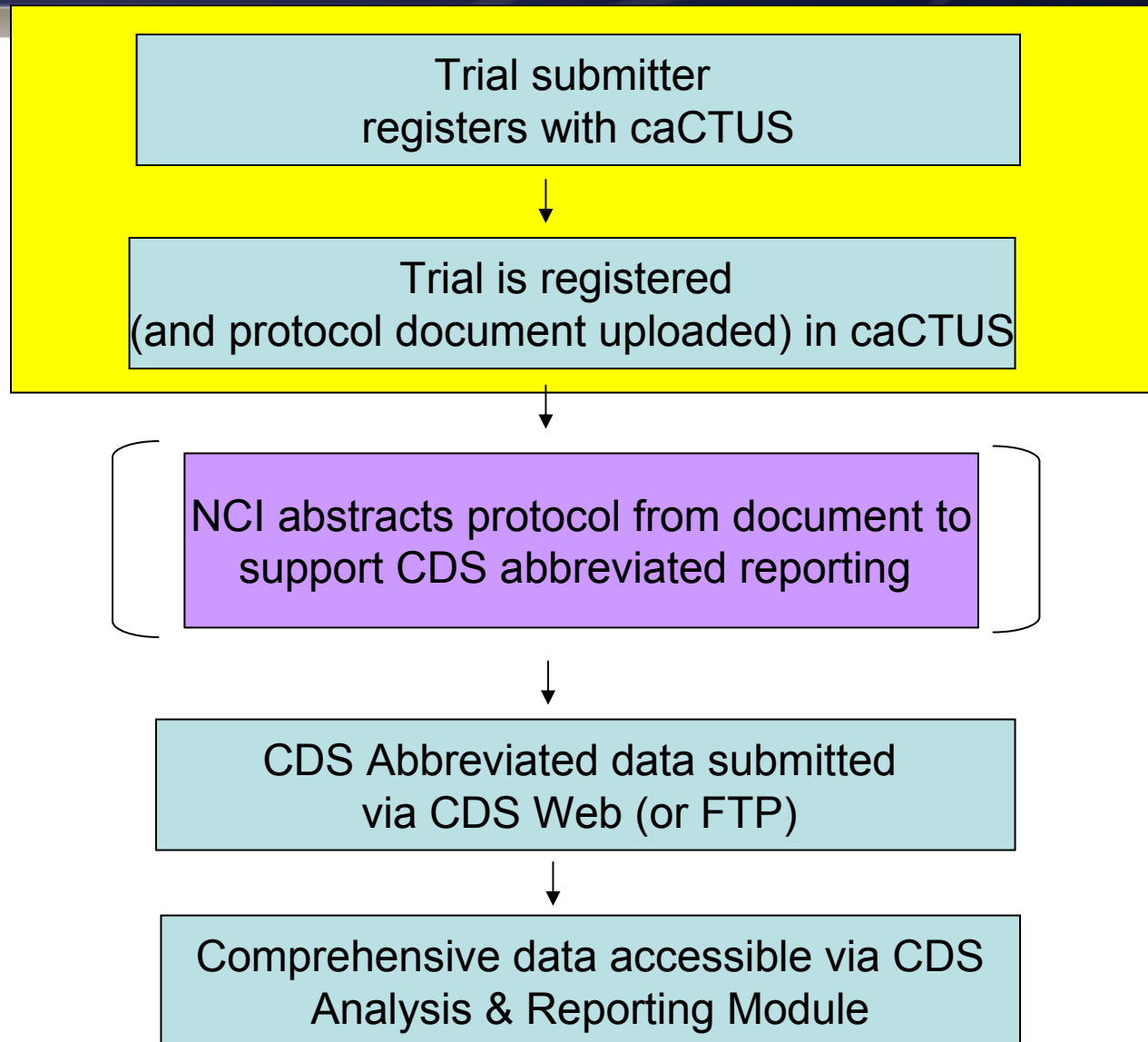


- **Establish central (NCI hosted) database for:**
 - Register all trials (and amendments)
 - Regularly submit accrual and demographic data
- **Provide access to data and reporting to authorized users**
- **Eliminate redundant reporting**
 - Generate Summary 4
 - Report to PDQ
 - Report to ClinicalTrials.gov

Proposed First Iteration of CTDB




Proposed First Iteration of CTDB



Cancer Clinical Trial Unified System




**National Cancer Institute**


**caCTUS™** Cancer Clinical Trial Unified System

caCTUS™

- Home
- Search Protocols
- Add a Protocol
- Login/Register
- Help


QUICK LINKS

-  [National Cancer Institute \(NCI\)](#)
-  [NCI Center for Bioinformatics \(NCICB\)](#)
-  [caBIG™ - Cancer Biomedical Informatics Grid™](#)



Welcome to caCTUS

Cancer Clinical Trial Unified System (caCTUS™) is a registry system for cancer clinical trial protocols that gives you the tools to:

- [Search for clinical trial protocols](#) submitted by members of the [caBIG™ community](#). You can view detailed protocol information such as the title, NCI and local identification numbers, study phase, study status, principal investigators, and more.
- [Submit your clinical trial protocols](#) and join our community of contributing scientists.
- [Login/register](#) to enter protocol details into the system.

Submitter Self Registration – Instant Access



National Cancer Institute



caCTUS™ Cancer Clinical Trial Unified System

caCTUS™

Home

Search Protocols

Add a Protocol

Login/Register

Help

QUICK LINKS

National Cancer Institute (NCI)

NCI Center for Bioinformatics (NCICB)

caBIG™ – Cancer Biomedical Informatics Grid™

My Account

[Help](#)

You may update your account information. Please note: asterisks (*) indicate required fields.

Login Information

Email: *

Password: *

Re-type Password: *

Your Account Profile

First Name: *

Middle Name:

Last Name: *

Street Address:

City:

State: *

Country: *

Zip/Postal Code:

Phone:

Select Role: *

Affiliate Organization: *

[\(Add New\)](#)

Trial Registration and Protocol Document Upload



National Cancer Institute



caCTUS™ Cancer Clinical Trial Unified System

caCTUS™

Home

Search Protocols

Add a Protocol

Logout

Help

QUICK LINKS

National Cancer Institute (NCI)

NCI Center for Bioinformatics (NCICB)

caBIG™ - Cancer Biomedical Informatics Grid™

Add a Protocol

Help

Add a protocol into caCTUS by submitting this form. Please note: asterisks (*) indicate required fields.

Protocol Details

Local Protocol ID: *

Monitoring Code: *

Protocol Title: *

Protocol Document: *

Type: *

Phase: *

Status: *

Current Status Date: * (mm/dd/yyyy)

Protocol Visibility: * ☒ Private ☐ Public

Lead Organization/Principal Investigator

Lead Organization: *

[\(Add New\)](#)

Lead Organization Name:

Cancel

Principal Investigator: *

[\(Add New\)](#)

caCTUS Protocol Registration Data Elements (Current – subject to curation)



- **Local Protocol ID (CDE ID: 2003300)**
- **Monitoring Code (CDE ID: 2182974)**
- **Protocol Title (CDE ID: 2182451)**
- **Protocol document – this is the actual document**
- **Trial Type (CDE ID: 2675107)**
- **Trial Phase (CDE ID: 2183023)**
- **Current Status (CDE ID: 2183054)**
- **Current Status date (CDE ID: 2608320)**
- **Lead Organization (CDE ID: 2152)**
- **Principal Investigator (CDE ID: 2183587 & 2183589)**

caCTUS CDEs in caDSR

CDE Browser - Microsoft Internet Explorer

Address: http://codebrowser.nci.nih.gov/CDEBrowser/

National Cancer Institute U.S. National Institutes of Health | www.cancer.gov

caDSR

Search Results Search within results

Results fewer than expected? Check Search Preferences

Download Data Elements to Excel Download Data Elements as XML

Sort order: (Default) Registration Status>>Workflow Status>>Long Name (Ascending)

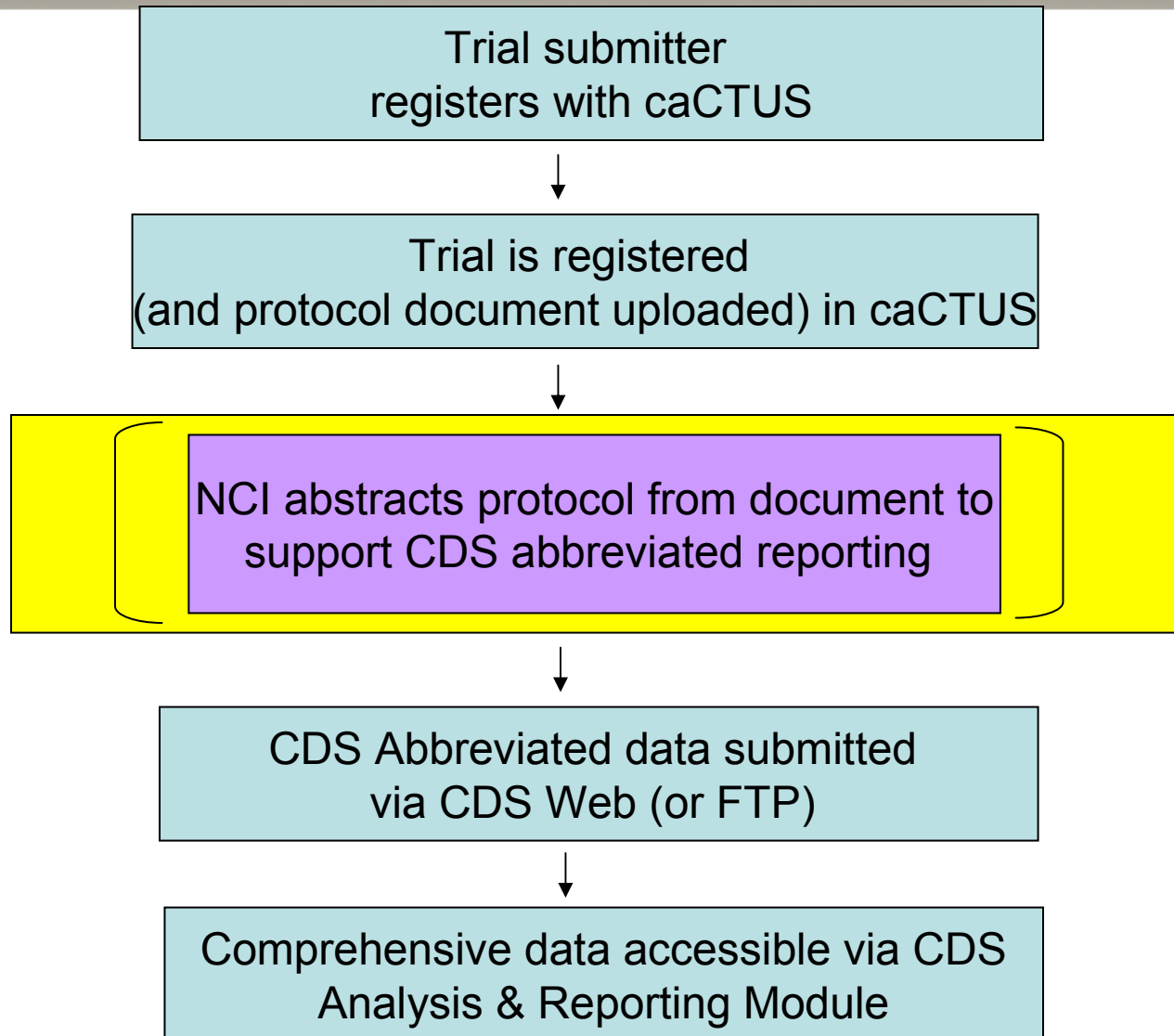
Add to CDE Cart Add to CDE Compare List Compare CDEs 1 - 10 of 10

<input type="checkbox"/>	Long Name	Protected Question Text	Owned By	Used By Context	Registration Status	Workflow Status	Public ID	Version
<input type="checkbox"/>	Organization Name	Organization Name	CTEP	DCR, NDCR, caBIG	Standard	RELEASED	2162	2.31
<input type="checkbox"/>	Clinical Trial Type Code	Type	caBIG		Qualified	RELEASED	2675107	1.0
<input type="checkbox"/>	Principal Investigator First Name	PI First Name	CCR	caBIG	Qualified	RELEASED	2169587	1.0
<input type="checkbox"/>	Principal Investigator Last Name	PI Last Name	CCR	caBIG	Qualified	RELEASED	2183589	1.0
<input type="checkbox"/>	Protocol Long Title Text	Protocol Long Title	CCR	CP, SPOREx, caBIG	Qualified	RELEASED	2182451	1.0
<input type="checkbox"/>	Protocol Monitor Code	Protocol Monitor	CCR	caBIG	Qualified	RELEASED	2182974	1.0
<input type="checkbox"/>	Protocol ID/Number	Protocol ID/Number	CCR	CP, SPOREx, caBIG	Qualified	RELEASED	2003300	4.0
<input type="checkbox"/>	Protocol Phase Code	Protocol Phase	CCR	caBIG	Qualified	RELEASED	2183023	1.0
<input type="checkbox"/>	Protocol Status Code	Status Code	CCR	caBIG	Qualified	RELEASED	2183054	1.0
<input type="checkbox"/>	Clinical Trial Protocol Status Date	Current Status Date	caBIG			DRAFT NEW	2608300	1.0

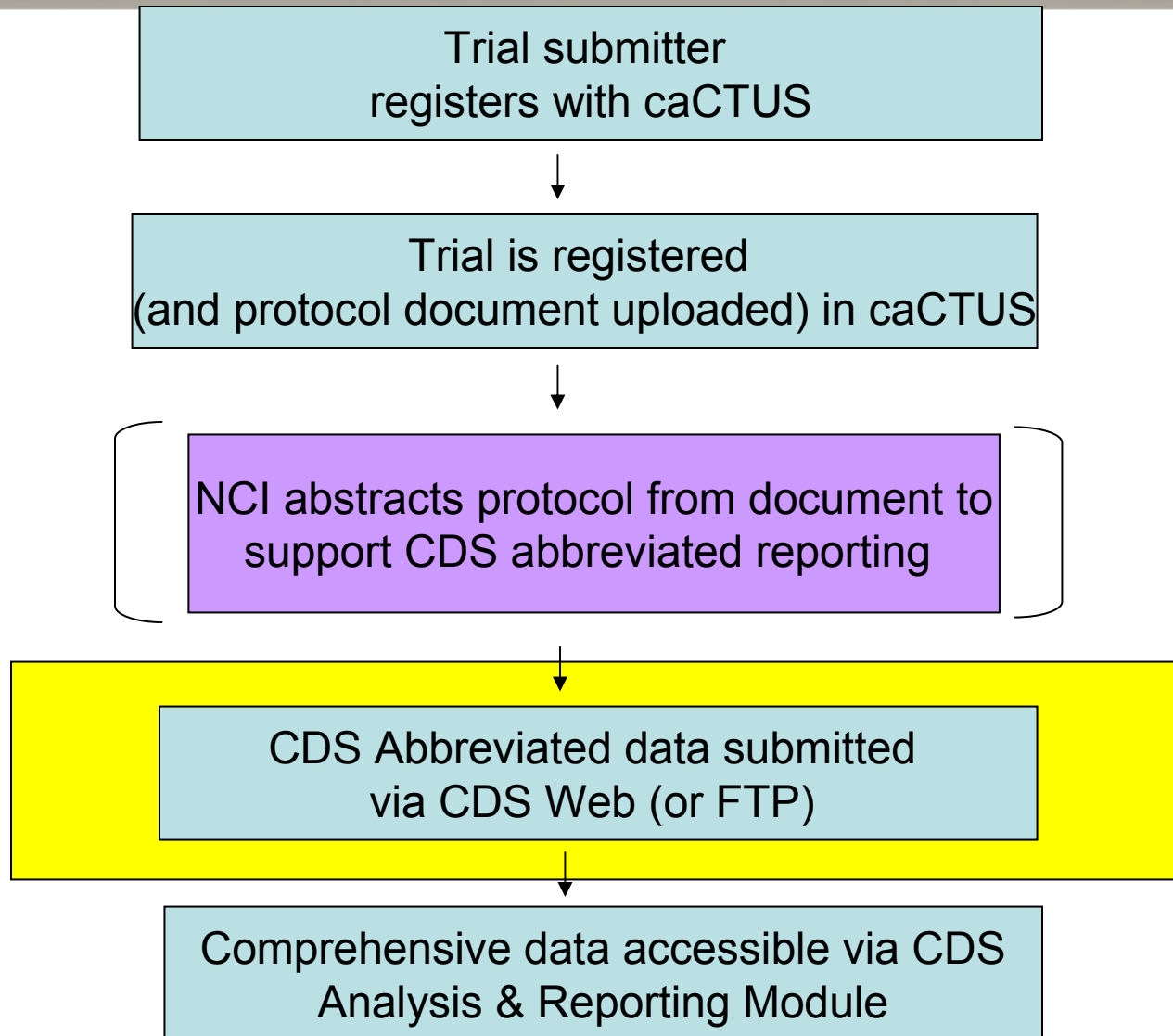
1 - 10 of 10

User: Public User Version 3.2 Build 7 Please note: CAPTURES ARE SUGGESTED TO BE USED FOR RESEARCH PURPOSES ONLY

Proposed First Iteration of CTDB



Proposed First Iteration of CTDB



CDUS Abbreviated Submission



- **An Abbreviated CDUS Data Set includes the following data elements:**
 - Protocol Status
 - NCI Protocol Number
 - Current Protocol Status
 - Current Protocol Status Date
 - Patient Accrual/Admin
 - Patient ID
 - Patient's Zip Code
 - Patient's Country Code
 - Patient's Birth Date
 - Patient's Gender
 - Patient's Ethnicity
 - Patient's Method of Payment
 - Date of Patient Entry
 - Registering Group Code (all studies with Group participation)
 - Registering Institution Code (mandatory as of April 1999)

Clinical Data System (CDS) Web Interface



Welcome to CDS-Web - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Address <https://cdsweb-qc.nci.nih.gov/cdsweb/loginPage.do> Go

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CDS WEB

Clinical Data System - Web

Welcome to CDS-Web

CDS - Web is a web based application which is the primary resource of clinical trial data for all of National Cancer Institute (NCI). CDS reports are submitted for all NCI sponsored trials (Phase 1, 2 and 3). This includes all:

- NCI sponsored Cooperative Group and Community Clinical Oncology Program (CCOP) Research Base treatment trials utilizing NCI supplied investigational agents and trials utilizing non-NCI agents (commercial or investigational).
- All NCI grant funded non-Cooperative Group (Cancer Center or other institution) trials (if CDS reporting is a grant requirement) utilizing non-NCI agents.
- All NCI sponsored Cooperative Group and CCOP Research Base non-treatment trials (accrual > 100 patients).

The Abbreviated CDS Data Set is limited to protocol administrative and patient demographic information. The Complete CDS Data Set contains the information found in the Abbreviated CDS Data Set, patient administrative information (e.g., registering institution code, patient treatment status), treatment information (e.g., agent administered, total dose per course), adverse event information (e.g., Adverse Event type, grade), and response information (e.g., response observed, date response observed).

Log on to CDS-Web

Username

Password

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Done Internet

CDS Submitter Information



Clinical Data System - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search

Address: [https://cdsweb-qa.nci.nih.gov/cdsweb-qa/cdusw00\\$cdusw_per_ogn_vw.startup](https://cdsweb-qa.nci.nih.gov/cdsweb-qa/cdusw00$cdusw_per_ogn_vw.startup) Go

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CDS WEB User: Stephanie Whitley Logoff Help

Please select the organization you wish to enter data for.

Organization(s) [Wayne State University](#)

Collections

Submission Date	Collection Status
07/31/2007	Active

Record 1 of 1

[ReQuery](#)

[New](#)

[Return to Collection Page](#)

Collection

Submission Date (MM/DD/YYYY):	07/31/2007
Cut-off Date(MM/DD/YYYY):	03/07/2007
Current Trial Status:	Active
Current Trial Status Date (MM/DD/YYYY):	04/06/2007
Submitter Last Name:	Whitley
Submitter First Name:	Stephanie
Submitter Middle Name:	
Submitter Phone:	012-234-6777
Submitter Fax:	
Submitter E-mail:	
Any additions or changes since last report:	<input checked="" type="radio"/> Yes <input type="radio"/> No

[Save](#) [Delete](#) [Clear](#) [New](#)

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Internet

CDS Patient Demographics

Clinical Data System : Data Entry - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Address [https://cdsweb-qc.nci.nih.gov/cdsweb-qc/cdusw03\\$.startup?z_collection_id=198&z_doc_id=6524608&z_](https://cdsweb-qc.nci.nih.gov/cdsweb-qc/cdusw03$.startup?z_collection_id=198&z_doc_id=6524608&z_) Go

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CDS WEB User: Stephanie Whitley [Logoff](#) | [Help](#)

DEMOTESTPROTOCOL18
(07/31/2007)

- Patient (1234, 04/1955)
 - Administrative Data
 - Baseline Abnormalities
 - Prior Therapies
 - Treatment Courses
 - Responses
 - Late Adverse Events
- Publications
- Correlative Studies
- Phase I End Points MTD
- Phase I End Points DLT
- Trial Comments
- Reports
- CTC Application
- View Collection
- View Protocol Selection
- Help

Patients

Select a patient to proceed

Patient ID	Birth Date (MM/YYYY)
1234	04/1955

Record 1 of 1

[ReQuery](#)

[Query](#)

[New](#)

Protocol Number: DEMOTESTPROTOCOL18

Patient Demographic Data

Patient ID: Enter the unique code assigned at the time of registration to this study. 1234

Birth Date (MM/YYYY): 04/1955

Gender: Female

Ethnicity: Not Hispanic or Latino

Races:

- ☒ Asian
- ☒ Black or African American
- ☐ American Indian or Alaska Native
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ Not Reported
- ☐ Unknown
- ☐ White

Country Name: United States

Zip Code: 20817

[Click to expand](#)

CDS Demographics/Accrual



Clinical Data System : Data Entry - Microsoft Internet Explorer

Address: https://cdsweb-qa.nci.nih.gov/cdsweb-qa/cdusw038_startup7z_collection_id=198&z_doc_id=652460&z_

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User: Stephanie Whitley Logoff | Help

DEMOTESTPROTOCOL18 (07/31/2007)

- Patient (1234: 04/1955)
 - Administrative Data
 - Baseline Abnormalities
 - Prior Therapies
 - Treatment Courses
 - Responses
 - Late Adverse Events
- Publications
- Correlative Studies
- Phase I End Points MTD
- Phase I End Points DLT
- Trial Comments
- Reports
- CTC Application
- View Collection
- View Protocol Selection
- Help

Patients

Select a patient to proceed

Patient ID	Birth Date (MM/YYYY)
1234	04/1955

Record 1 of 1

ReQuery

Query

New

☐ White

Country Name: United States

Zip Code: 20817

Payment Method:

Entry Date (MM/DD/YYYY): 04/03/2007

Registering Group:

Reg Group ID:

Registering Institution: Cobb Hospital and Medical Center

Reg Inst ID: GA076

Disease Category:

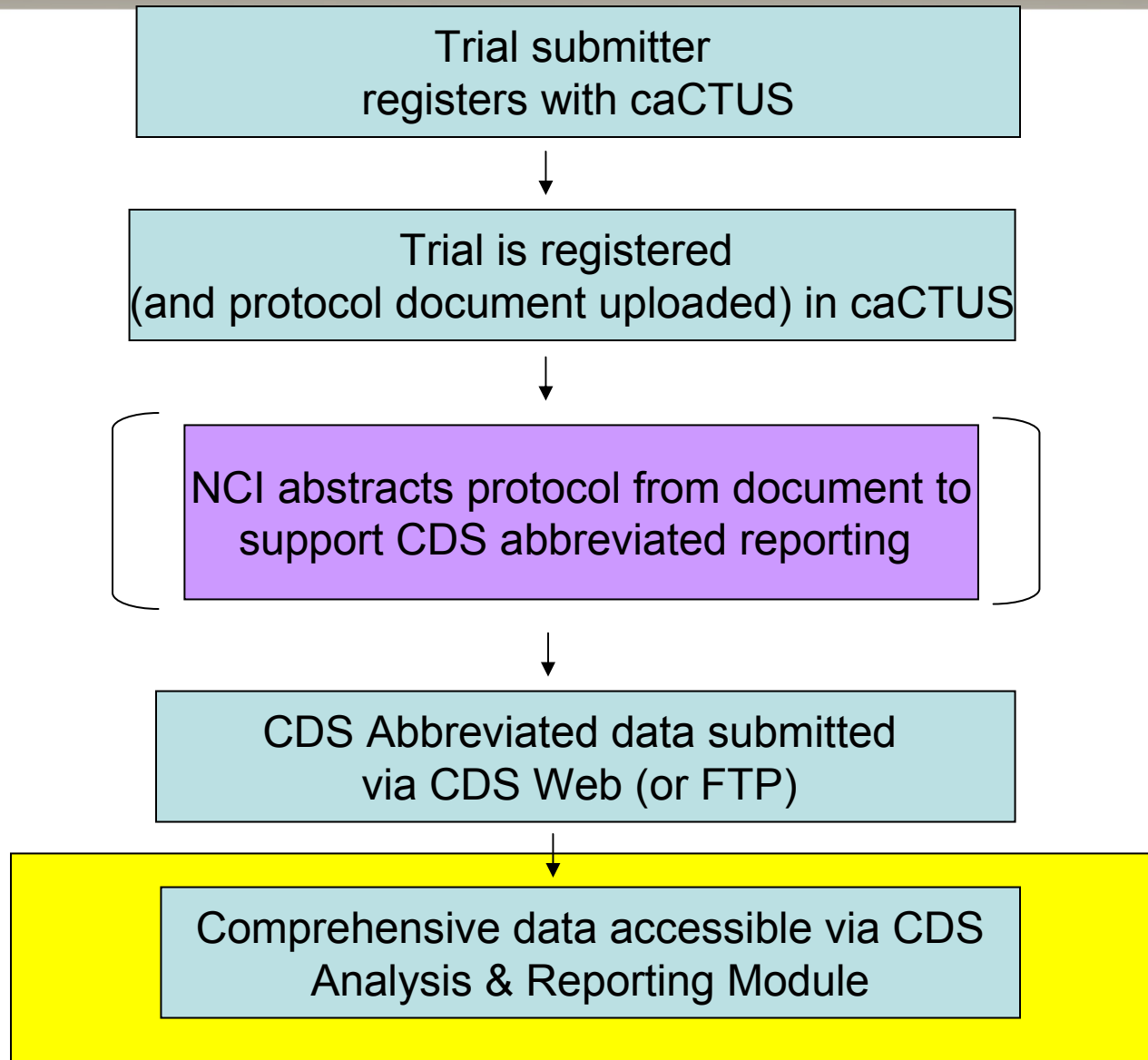
Disease Sub Category:

Disease Name:

Save Delete Clear New

All data elements in bold are mandatory

Proposed First Iteration of CTDB



CDS Analysis & Reporting ("Sharing" CTEP CDUS Reports)



National Cancer Institute

U.S. Nation Institutes of Health | www.cancer.gov



Clinical Data System – Analysis and Reporting

Welcome to CDS – AR

The Clinical Data System (CDS) Analysis and Reporting is a Web-based computer application for querying clinical data. The CDS AR enables the users to view and generate reports about various aspects of the clinical trial process. The CDS AR has a web based component used to query information from the CRIX Enterprise System database. It is designed to allow users to access clinical data based on roles and permissions.

Log on to CDS - AR

Click the Log-in button below to logon using Safe.



Log-on

Click [here](#) to log-in with a username and password.

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FIRSTGOV

Input Parameters for Protocol Query



CDS-AR - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Address <http://192.168.200.179:8992/cdsar/CDSPeraSelection.do?method=putInputParam&inParam=monitoringMethod&type=input> Go Links

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CDS-AR **CDS-AR > Select List of Parameters** **User: Test User1**
[Log Off](#) | [Help](#)

Input Parameter Output Parameter Results Saved Queries

Protocol

- Protocol Number
- Protocol Phase
- Current Trial Status
- Current Trial Status Date (From)
- Current Trial Status Date (To)
- Participation Type
- Monitoring Method**

Organization

- Organization Id
- Organization Name
- Organization Type

Agent

- Agent NSC/GPI Number
- Agent Name
- Agent Type

IND

- IND #

Disease

- MedDRA disease code
- Disease Term

Investigator

- PI/Investigator

Input Parameter(s)

Delete?	Parameter Name	Selected Values	Available Values
<input type="checkbox"/>	Monitoring Method	CDUS - Abbreviated CDUS - Complete	CDUS - Abbreviated CDUS - Complete CTMS (CDUS - Abbreviated) CTMS (CDUS - Complete)
<input type="checkbox"/>	Protocol Phase	I I/II II	I I/II II III
<input type="checkbox"/>	Current Trial Status	Active	Active Administratively Complete Approved Closed to Accrual

Search Delete Reset

Output Parameters for Protocol Query



CDS-AR - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Address <http://192.168.200.179:8992/cdsar/CDSParaSelection.do?method=putInputParam&inParam=agent&type=output> Go Links

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CDS-AR **CDS-AR > Select List of Parameters** User: Test User1 [Log Off](#) | [Help](#)

Input Parameter Output Parameter Results Saved Queries

Protocol

- Protocol Number
- Protocol Title
- Protocol Phase
- Current Trial Status
- Current Trial Status Date
- Participation Type
- Monitoring Method

Organization

- Organization Name

Agent

- Agent NSC/GPI Number**

IND

- IND #

Disease

- Disease(MedDRA)

Investigator

- PI/Investigator

Other

- Accrual
- Cut Off Date
- Activation Date

Output Parameter(s)

Delete?	Parameter Name	Display
<input type="checkbox"/>	Protocol Number	↓
<input type="checkbox"/>	Protocol Title	↑↓
<input type="checkbox"/>	Protocol Phase	↑↓
<input type="checkbox"/>	Current Trial Status	↑↓
<input type="checkbox"/>	Current Trial Status Date	↑↓
<input type="checkbox"/>	Monitoring Method	↑↓
<input type="checkbox"/>	Organization Name	↑↓
<input type="checkbox"/>	Agent NSC/GPI Number	↑

Search Delete Reset

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Done Internet

start 2 Microsoft... /cds_data/cd... Oracle Forms... CDS-AR - Mic... SQL Navigator Microsoft Po... 3:16 PM

Protocol Query Results (and Saved Queries)



CDS-AR - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites Refresh Mail Print Address Bar Links

Address http://wvp-skakar:8988/cdsreports/CD5PeraSelection.do

Input Parameter Output Parameter **Results** Saved Queries

Query Condition:
Monitoring Method = CDUS - Abbreviated, CDUS - Complete
AND Protocol Phase = I, I/II, II
AND Current Trial Status = Active

☐ Monitoring Method = CDUS - Abbreviated, CDUS - Complete
☐ Protocol Phase = I, I/II, II
☐ Current Trial Status = Active

Search Group OR Group AND Ungroup Save Query

Query Results [View in Excel]

Select	Protocol Number	Protocol Title
<input type="checkbox"/>	Protocol-20	A Phase I Trial of Weekly 17-Allylamino-17-Demethoxygeldanamycin
<input type="checkbox"/>	Protocol-10	A Phase I/II Dose-Finding Study to Determine the Safety, Tolerability, and Anti-Leukemic Effects of STI571 in Combination with Interferon
<input type="checkbox"/>	Protocol-1	A Randomized Phase II Trial of EPOCH Given Either Concurrently or Sequentially with Rituximab in Patients with Intermediate or High Grade
<input type="checkbox"/>	Protocol-2	A Phase I/II Trial of SGN-00101 in the Treatment of High-Grade Anal Intraepithelial Neoplasia (AIN) in HIV-Positive Individuals

Total Pages: 1 Total Records:

Select All DeSelect All Generate Report Search Again

Done Local intranet

start 2 Microsoft... /cds_data/cd... Oracle Forms... SQL Navigator Microsoft Po... CDS-AR - Mic... 3:23 PM

Available Reports for Selected Protocols



CDS-AR - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites Refresh Print Mail News RSS Feeds

Address http://wvp-skakar:8988/cdsreports/CDSPeraSelection.do Go Links

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CDS-AR

CDS-AR > Reports

User: Test User1
Log Off | Help

Query Condition:
Monitoring Method = CDUS - Abbreviated, CDUS - Complete
AND Protocol Phase = I,I/II,II
AND Current Trial Status = Active

CDS-AR Reports

- ☐ **Accrual**
 - ☐ Accrual By Protocol
 - ☐ Accrual By Gender/Race - Protocols
 - ☐ Accrual By Gender/Race - Organizations
 - ☐ Accrual By Institution
- ☐ **Adverse Event**
 - ☐ Adverse Event
 - ☐ Patient Specific Information
 - ☐ Subgroup Adverse Event
 - ☐ Subgroup Response and Adverse Event
- ☐ **Correlative Study**
 - ☐ Correlative Study
- ☐ **Demographics**
 - ☐ Patient Demographic - Single Protocol
 - ☐ Population Demographics
- ☐ **Dropout**
 - ☐ Dropout
- ☐ **Publication**
 - ☐ Publications

Done Local intranet

start 2 Microsoft... /cds_data/cd... Oracle Forms... SQL Navigator Microsoft Po... CDS-AR - Mic... 3:26 PM

Next Steps



- **Develop new NCI Policy to ensure all trials are reported**
 - CCCT led activity
- **Assemble NCI Policy Implementation Team to address:**
 - “Legacy” data migration
 - Protocol abstraction
- **Ensure generation of Summary 4 and PDQ and ClinicalTrials.gov submissions**
 - Summary 3 will require non-accrual data
- **Develop timeline to coordinate activities**

- Meeting Objectives
- Introductions
- SIG Meeting Schedule
- Overview of CTMS Workspace
- Overview of Reporting / Sharing SIG
- Clinical Trials Database (CTDB)
- **Comment, Feedback, Questions**
- **Review of Action Items**

Thank you! Q & A

